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(54) **HEART VALVE IMPLANT**

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See application file for complete search history.

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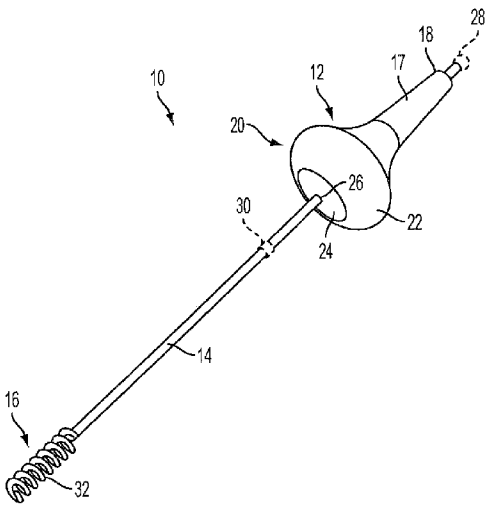
(57) **ABSTRACT**

A method according to one embodiment may include providing a heart valve implant including an anchor capable of engaging coronary tissue, a shaft coupled to said anchor, and a valve body coupled to said shaft. The method may further include at least partially collapsing the heart valve implant and percutaneously inserting the heart valve implant into a heart. The percutaneously inserted implant may be secured within the heart and may then be expanded. Of course, many alternatives, variations, and modifications are possible without departing from this embodiment.

17 Claims, 15 Drawing Sheets



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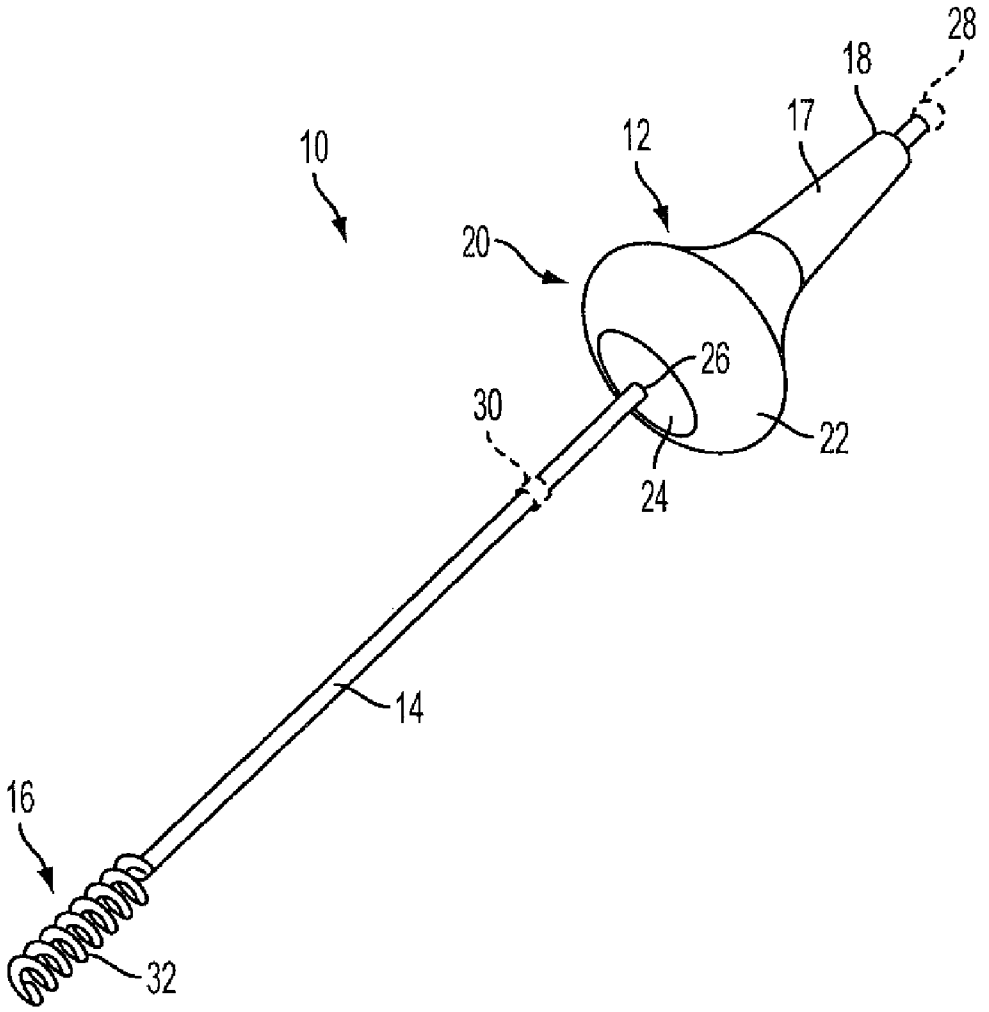

FIG. 1

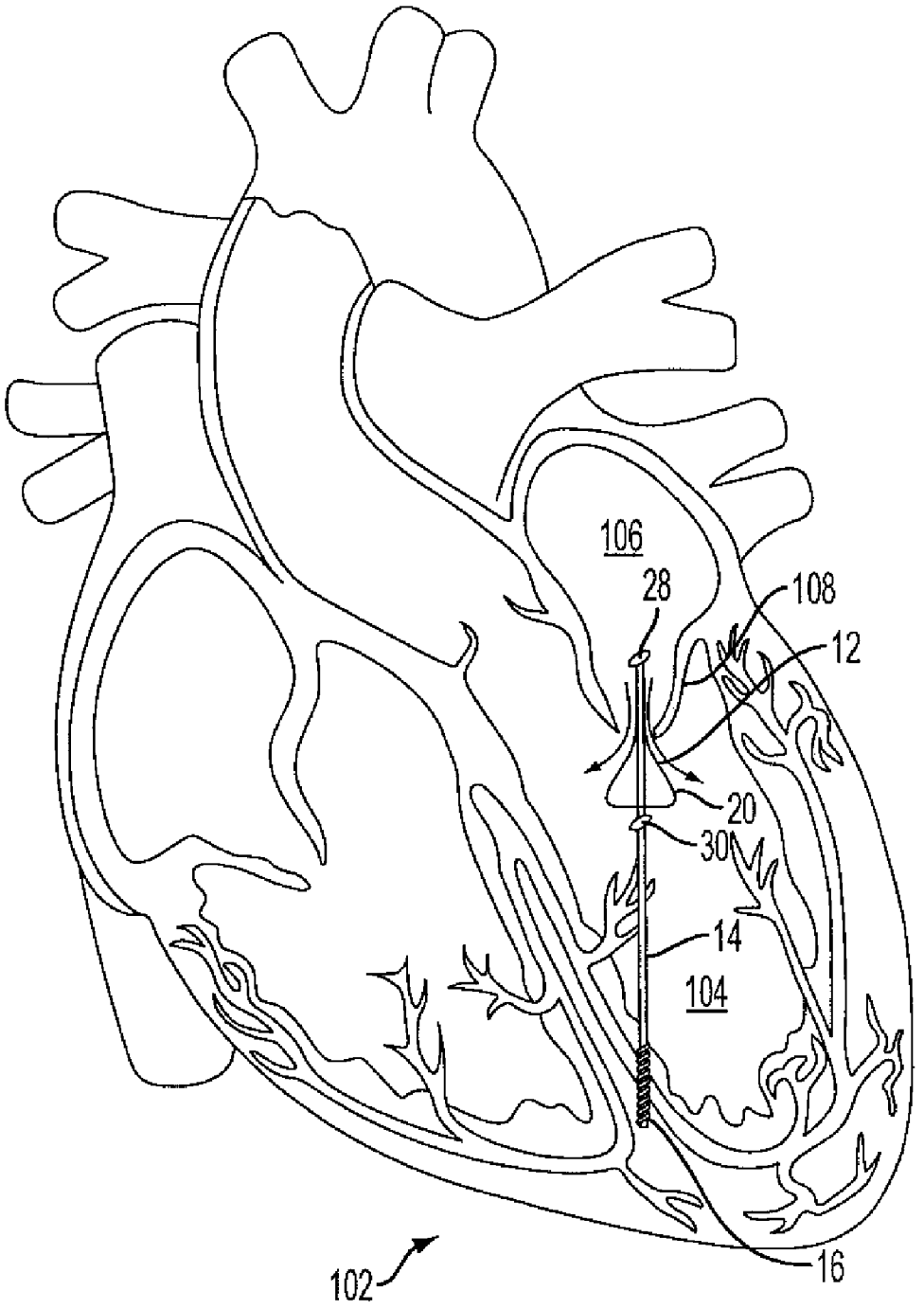

FIG. 2

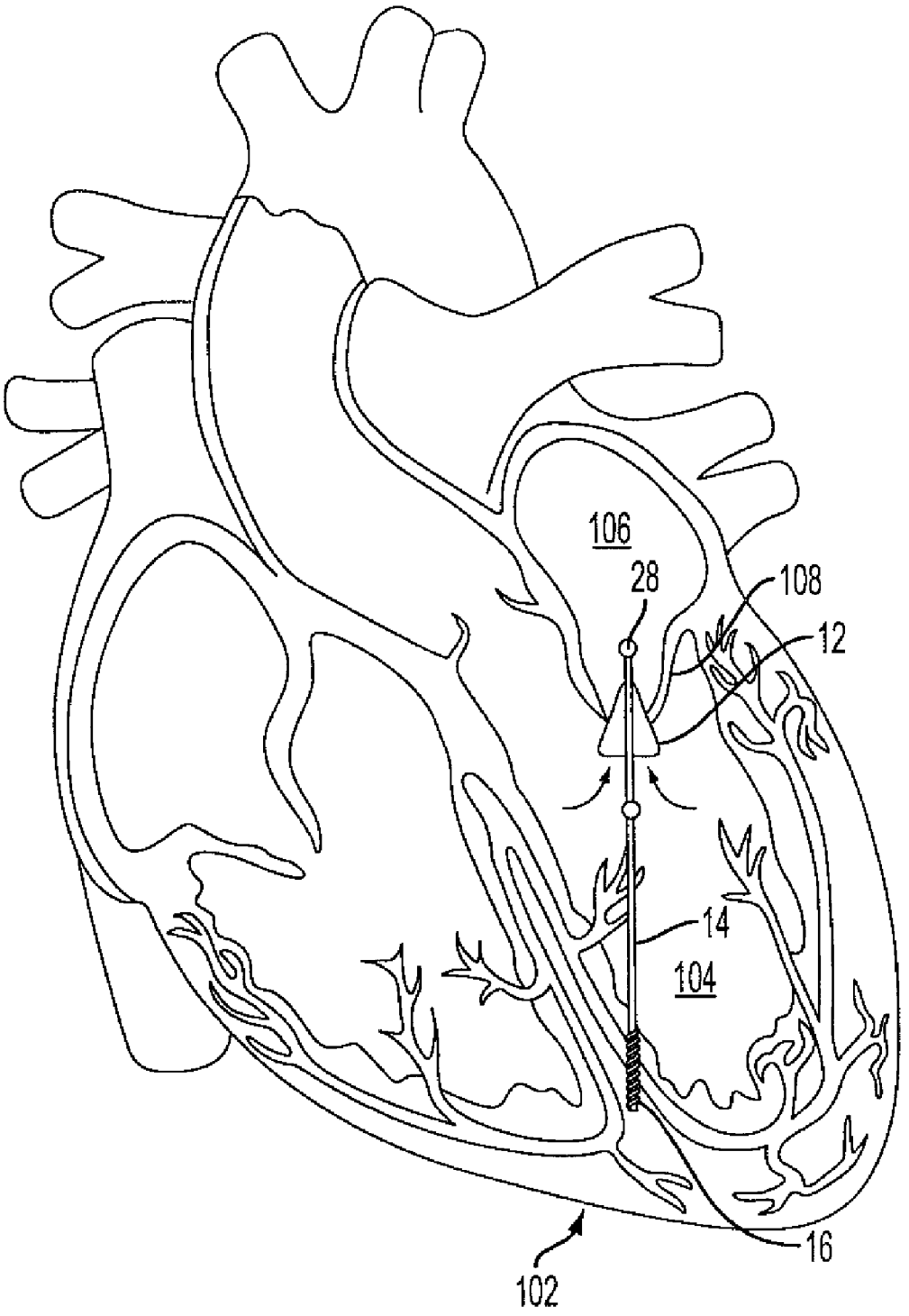

FIG. 3

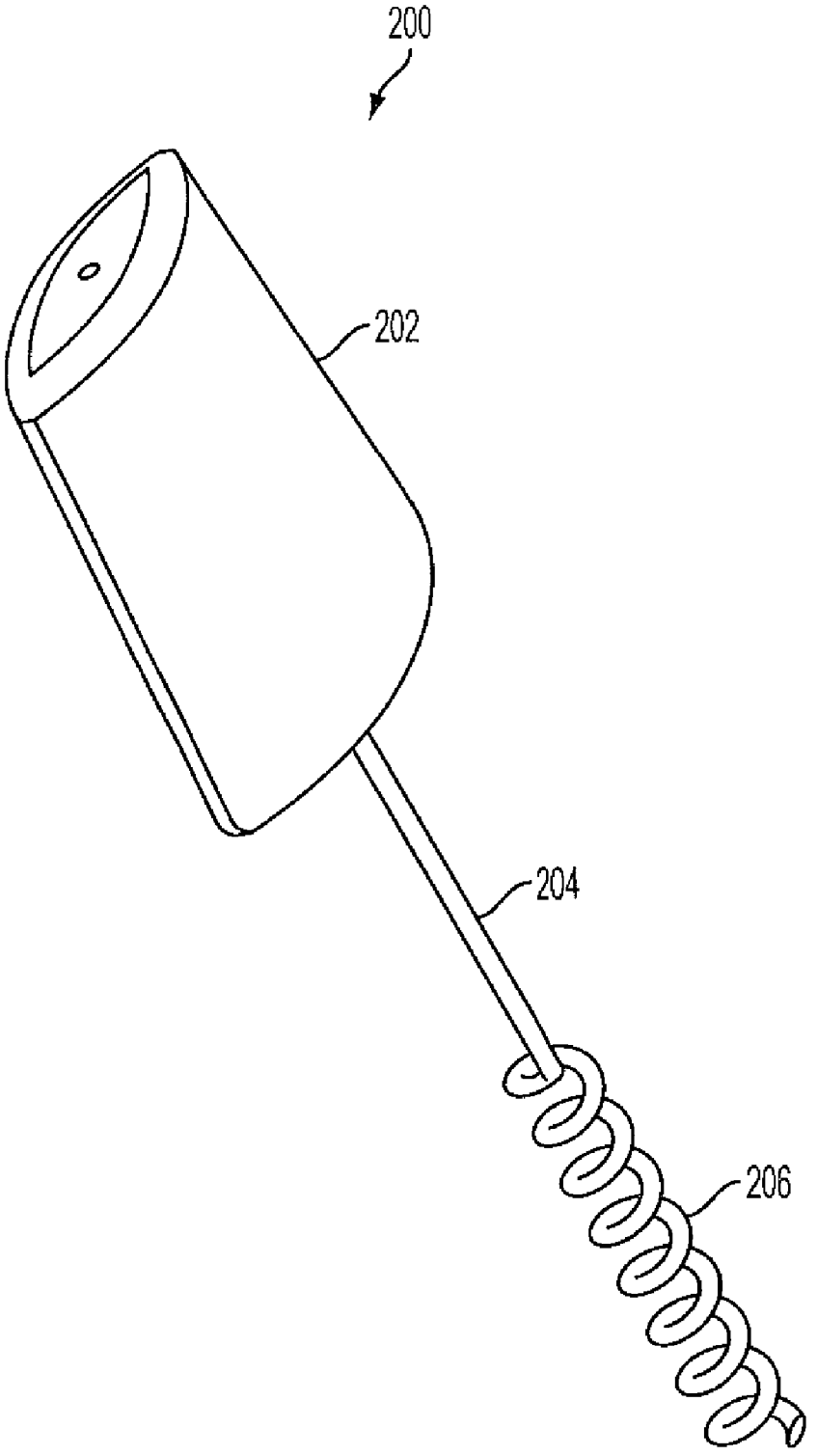

FIG. 4

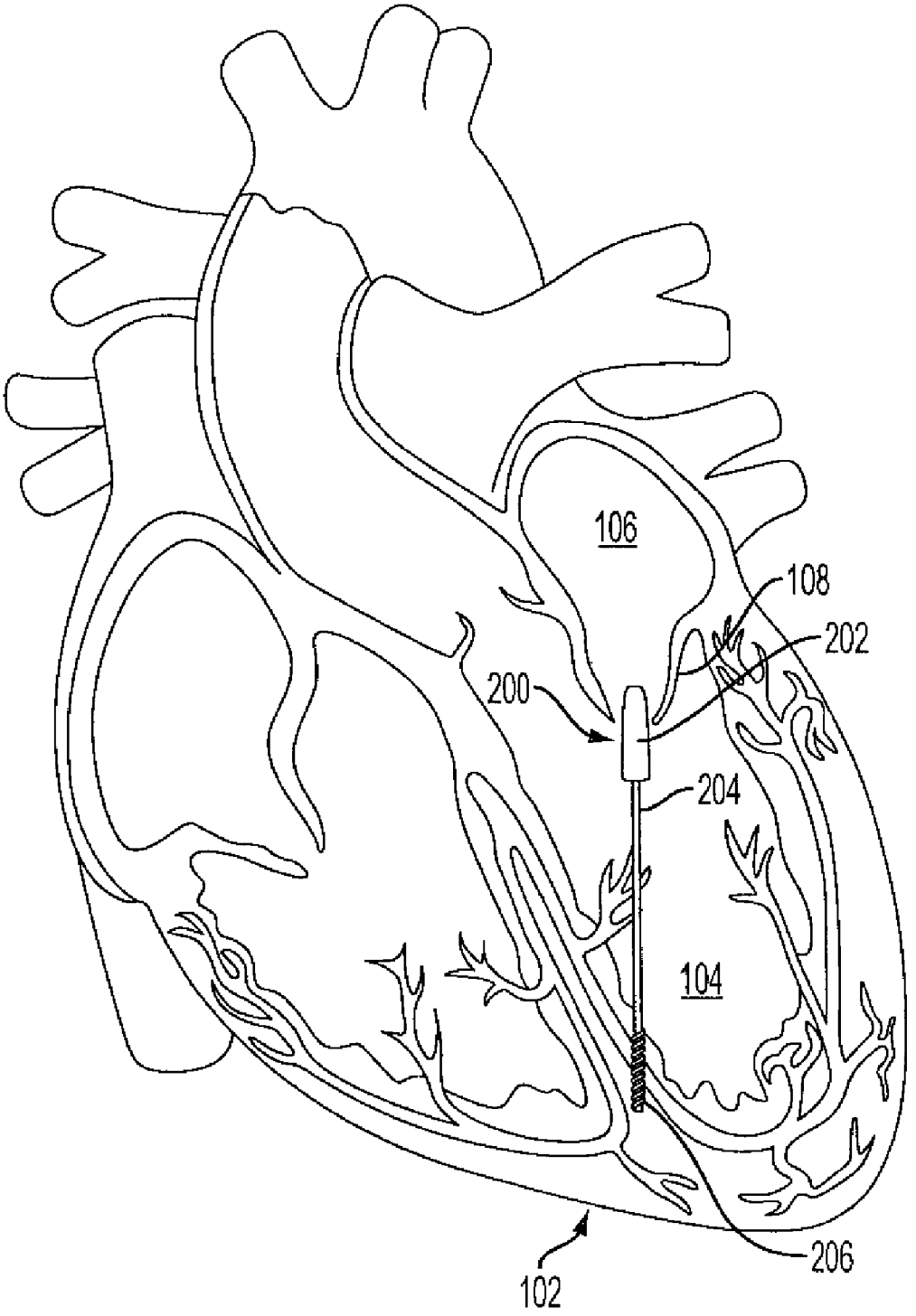

FIG. 5

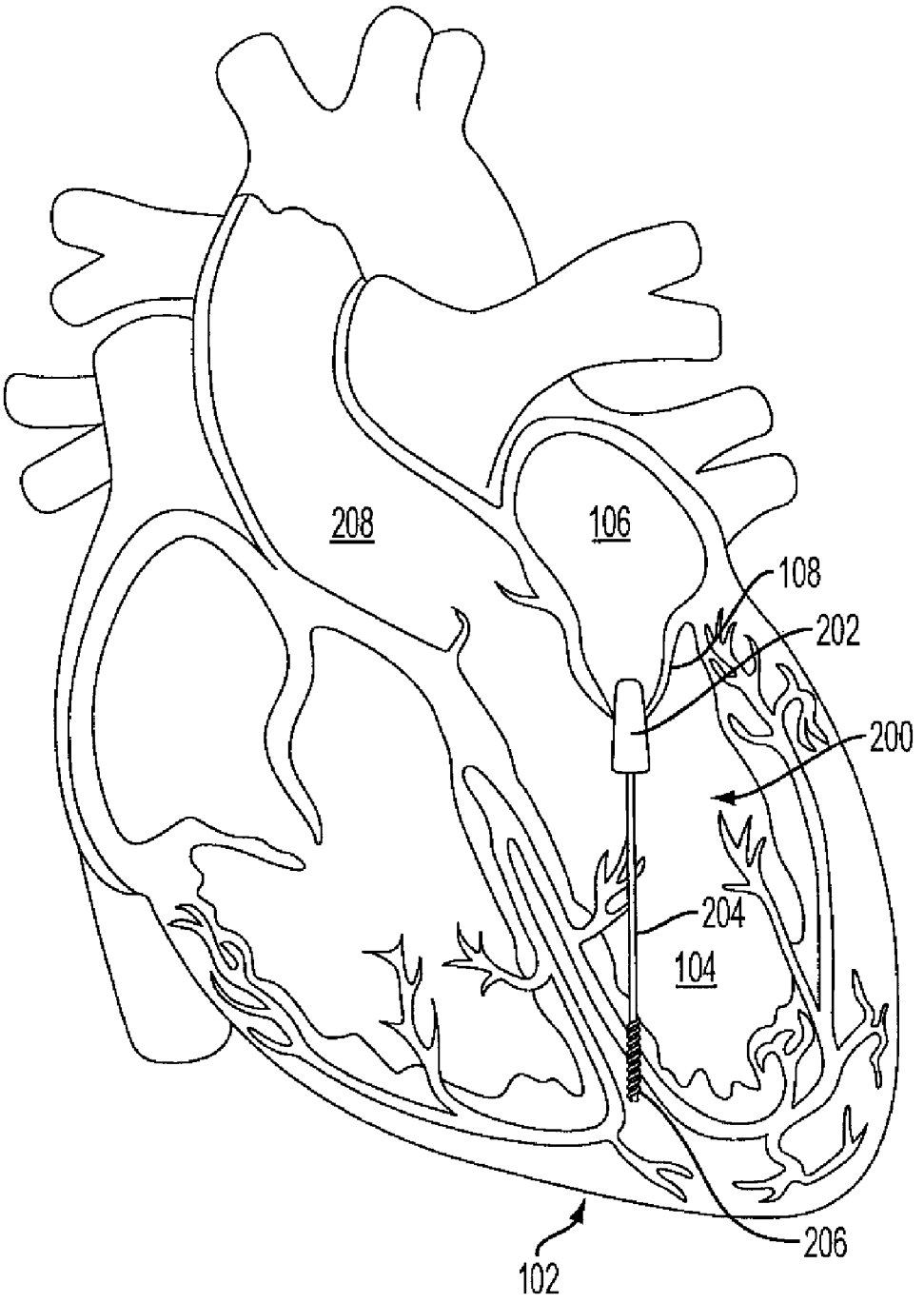

FIG. 6

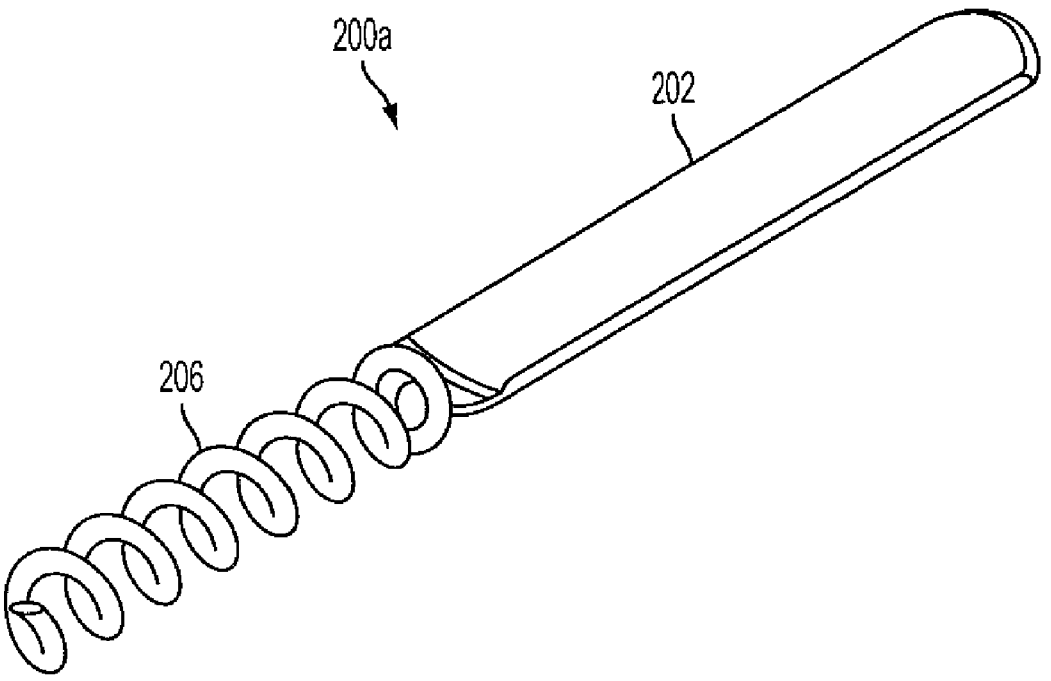

FIG. 7

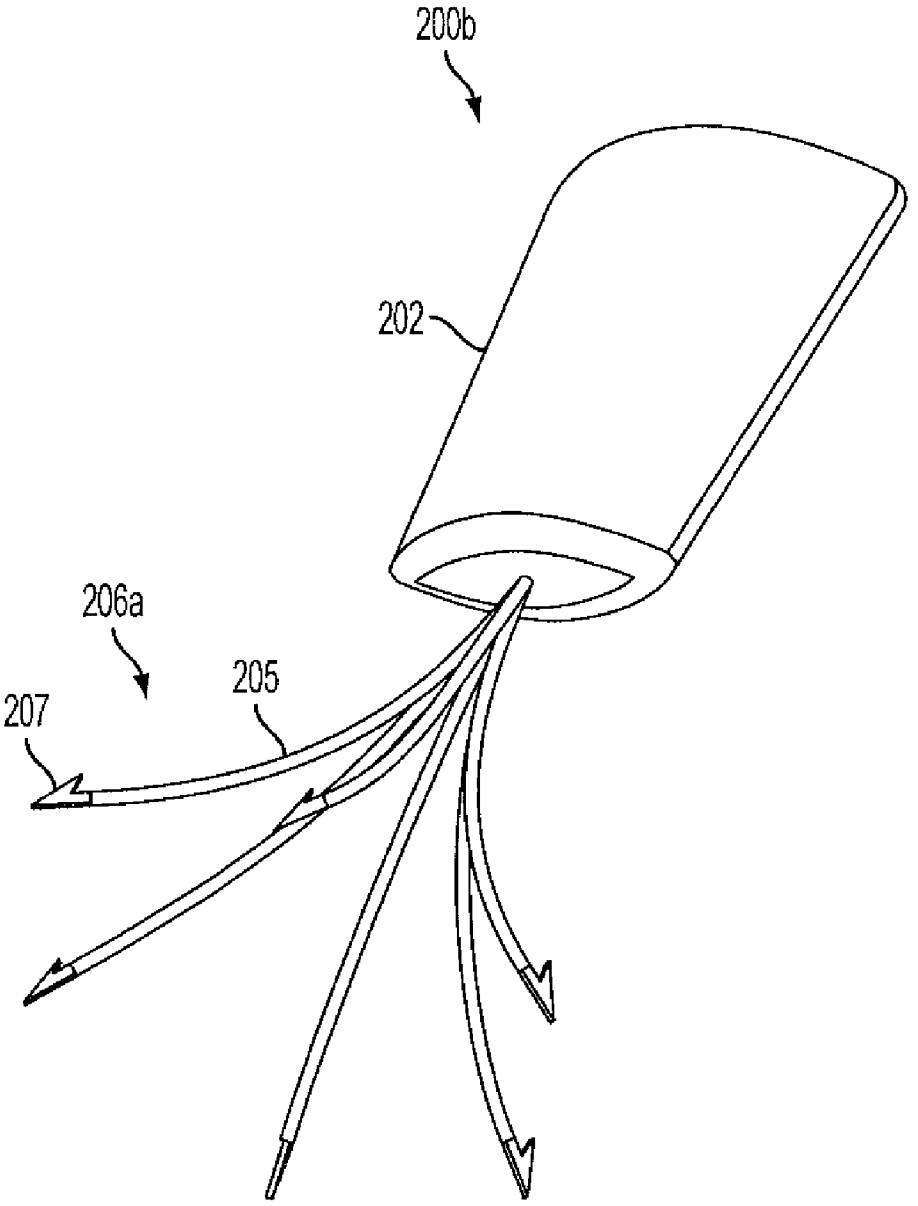

FIG. 8

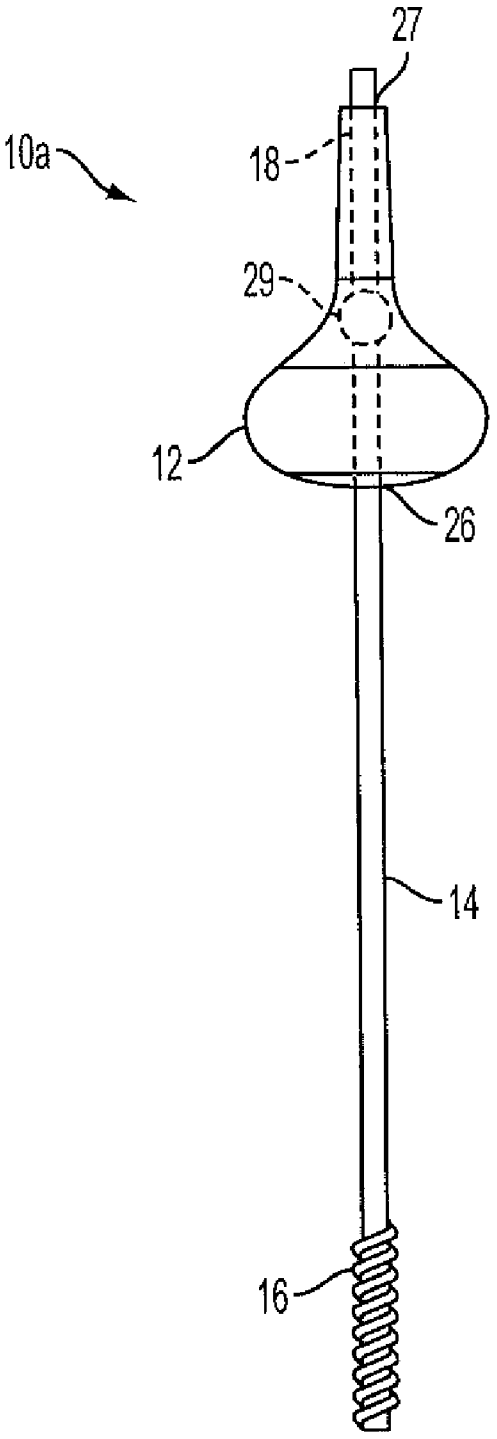

FIG. 9

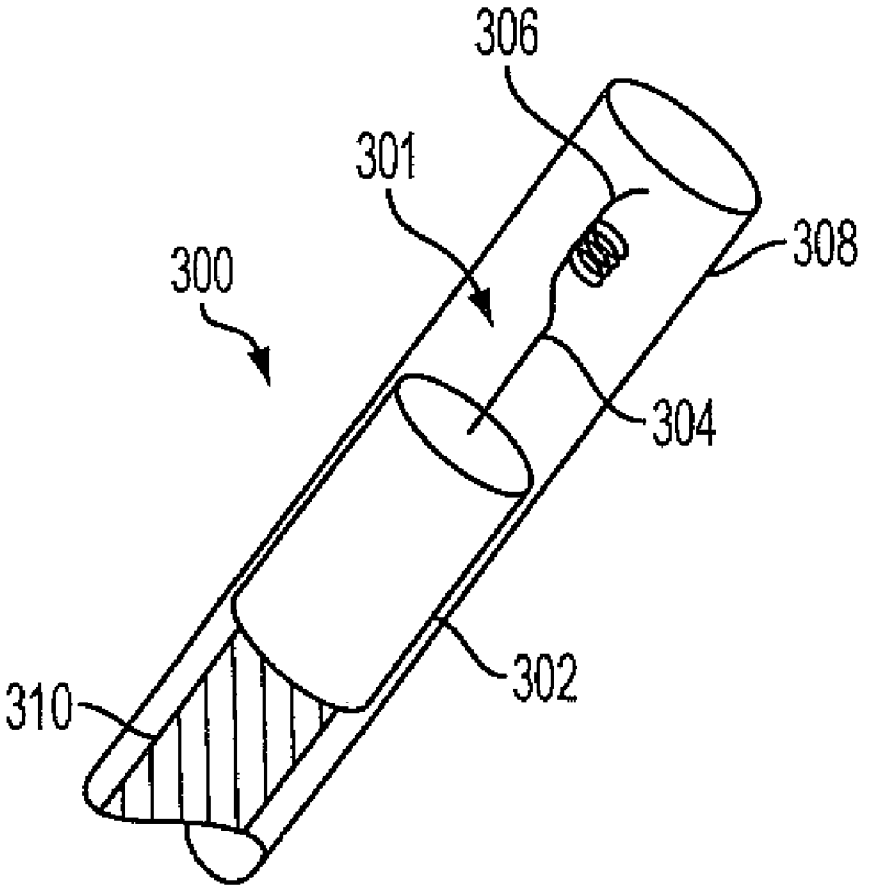

FIG. 10

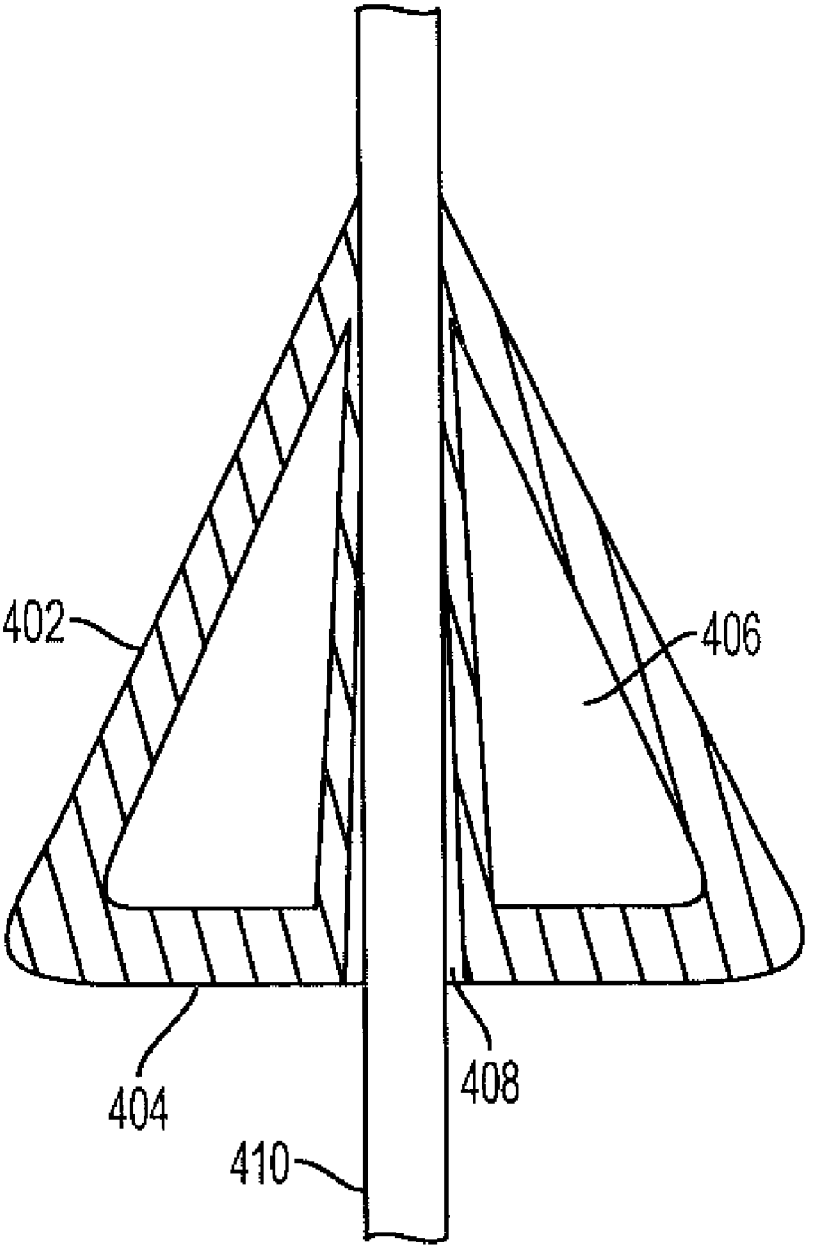

FIG. 11

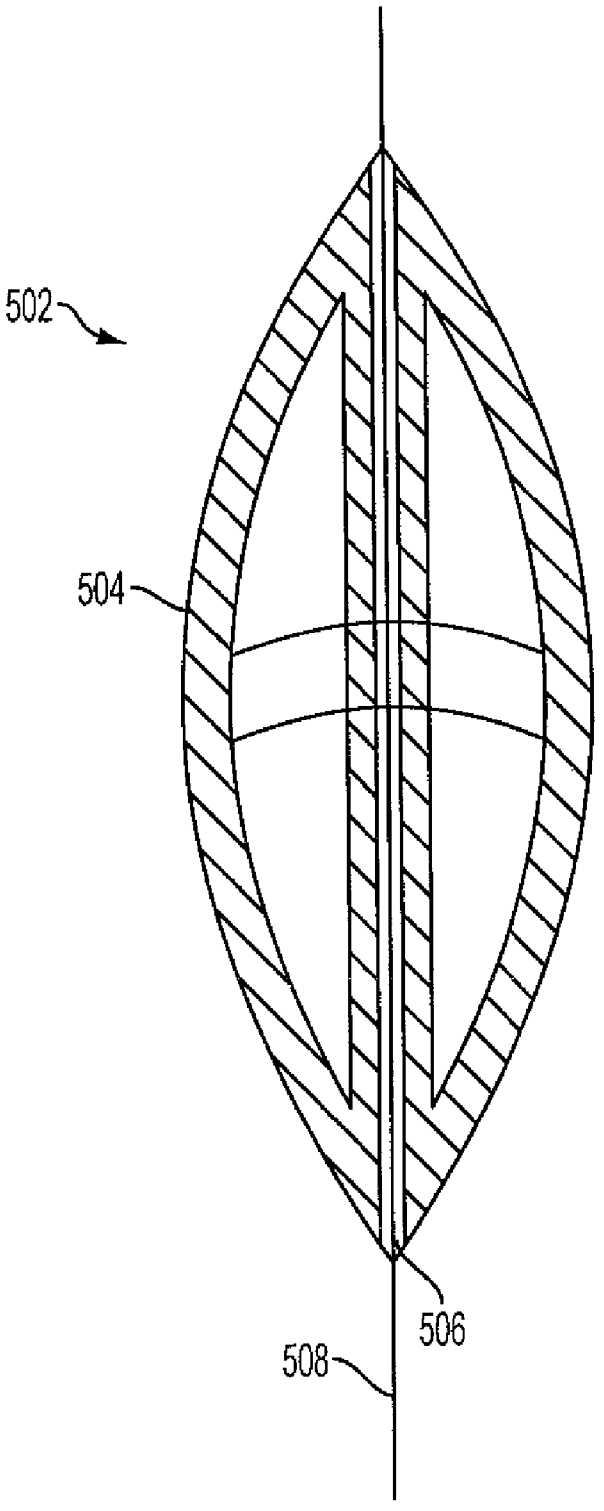

FIG. 12

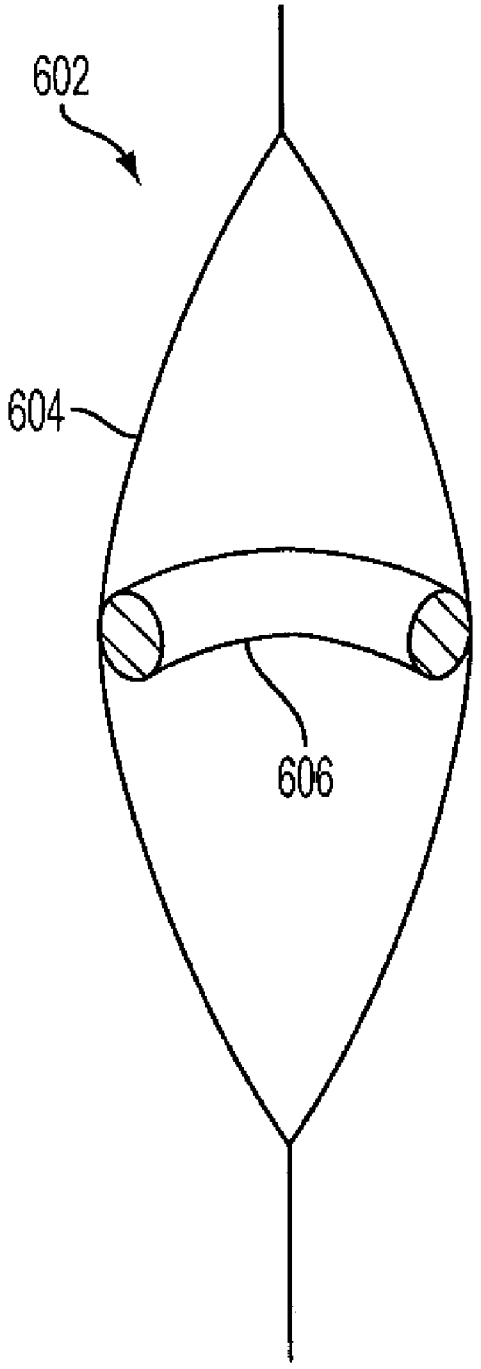

FIG. 13

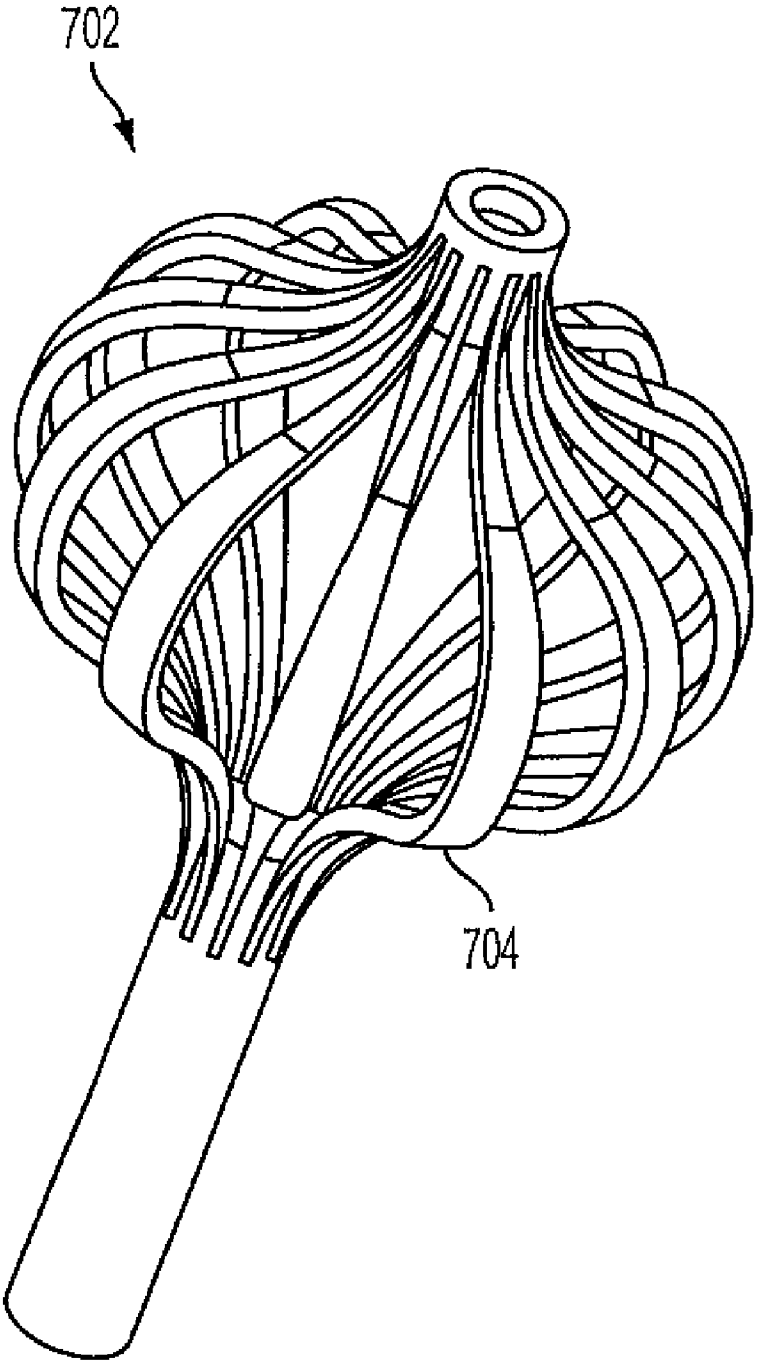

FIG. 14

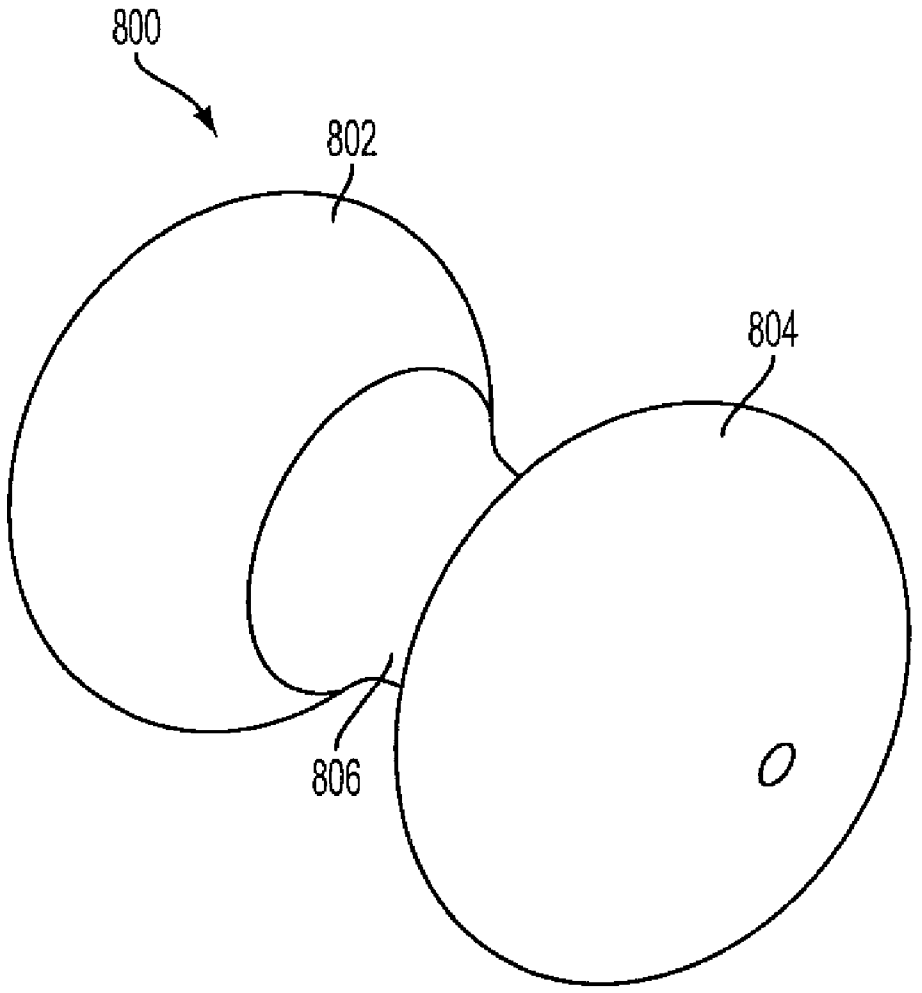

FIG. 15

HEART VALVE IMPLANT

FIELD

The present disclosure relates to the repair and/or correction of dysfunctional heart valves, and more particularly pertains to heart valve implants and systems and methods for delivery and implementation of the same.

BACKGROUND

A human heart has four chambers, the left and right atrium and the left and right ventricles. The chambers of the heart alternately expand and contract to pump blood through the vessels of the body. The cycle of the heart includes the simultaneous contraction of the left and right atria, passing blood from the atria to the left and right ventricles. The left and right ventricles then simultaneously contract forcing blood from the heart and through the vessels of the body. In addition to the four chambers, the heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves may become damaged, or otherwise fail to function properly, resulting in their inability to properly close when the downstream chamber contracts. Failure of the valves to properly close may allow blood to flow backward through the valve resulting in decreased blood flow and lower blood pressure.

Mitral regurgitation is a common variety of heart valve dysfunction or insufficiency. Mitral regurgitation occurs when the mitral valve separating the left coronary atrium and the left ventricle fails to properly close. As a result, upon contraction of the left ventricle blood may leak or flow from the left ventricle back into the left atrium, rather than being forced through the aorta. Any disorder that weakens or damages the mitral valve can prevent it from closing properly, thereby causing leakage or regurgitation. Mitral regurgitation is considered to be chronic when the condition persists rather than occurring for only a short period of time.

Regardless of the cause, mitral regurgitation may result in a decrease in blood flow through the body (cardiac output). Correction of mitral regurgitation typically requires surgical intervention. Surgical valve repair or replacement is carried out as an open heart procedure. The repair or replacement surgery may last in the range of about three to five hours, and is carried out with the patient under general anesthesia. The nature of the surgical procedure requires the patient to be placed on a heart-lung machine. Because of the severity/complexity/danger associated with open heart surgical procedures, corrective surgery for mitral regurgitation is typically not recommended until the patient's ejection fraction drops below 60% and/or the left ventricle is larger than 45 mm at rest.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantage of the claimed subject matter will be apparent from the following description of embodiments consistent therewith, which description should be considered in conjunction with the accompanying drawings, wherein:

FIG. **1** is a perspective view of an embodiment of a mitral valve implant consistent with the present disclosure;

FIG. **2** depicts an embodiment mitral valve implant consistent with the present disclosure implanted within a heart in an open position;

FIG. **3** depicts an embodiment of a mitral valve implant consistent with the present disclosure implanted within a heart in a closed position;

FIG. **4** depicts another embodiment of a mitral valve implant consistent with the present disclosure;

FIG. **5** depicts the mitral valve implant of FIG. **4** implanted within a heart in an open position;

FIG. **6** depicts the mitral valve implant of FIG. **4** implanted within a heart in a closed position;

FIG. **7** shows another embodiment of a mitral valve implant consistent with the present disclosure;

FIG. **8** shows an embodiment of a mitral valve implant including a barb anchor portion consistent with the present disclosure;

FIG. **9** depicts another embodiment of a translating mitral valve implant consistent with the present disclosure;

FIG. **10** schematically shows and embodiment of a percutaneous mitral valve implant delivery system consistent with the present disclosure;

FIG. **11** is a cross-sectional view of an embodiment of an inflatable valve body consistent with the present disclosure;

FIG. **12** is a cross-sectional view of an embodiment of an expandable valve body consistent with the present disclosure;

FIG. **13** is a cross-sectional view of an embodiment of an expandable valve body consistent with the present disclosure including a recoverably deformable rib;

FIG. **14** is a cross-sectional view of another embodiment of an expandable valve body consistent with the present disclosure including recoverably deformable stringers; and

FIG. **15** is perspective view of a valve body of yet another embodiment of a mitral valve implant consistent with the present disclosure.

DESCRIPTION

The present disclosure relates to a heart valve implant. A heart valve implant herein may suitably be used in connection with the treatment and/or correction of a dysfunctional or inoperative heart valve. One suitable implementation for a heart valve implant consistent with the present disclosure is the treatment of mitral valve regurgitation. For the ease of explanation, the heart valve implant herein is described in terms of a mitral valve implant, such as may be used in treating mitral valve regurgitation. However, a heart valve implant consistent with the present disclosure may be employed for treating and/or correcting other dysfunctional or inoperative heart valves. The present disclosure should not, therefore, be construed as being limited to use as a mitral valve implant.

Generally, a heart valve implant consistent with the present invention may interact with at least a portion of an existing heart valve to prevent and/or reduce regurgitation. For example, at least a portion of one or more cusps of the heart valve may interact with, engage, and/or seal against at least a portion of the heart valve implant when the heart valve is in a closed condition. The interaction, engagement and/or sealing between at least a portion of at least one cusp and at least a portion of the heart valve implant may reduce and/or eliminate regurgitation in a heart valve, for example, providing insufficient sealing, including only a single cusp, e.g., following removal of a diseased and/or damaged cusp, and/or having a ruptured cordae. A heart valve implant consistent with the present disclosure may be used in connection with various additional and/or alternative defects and/or deficiencies.

Referring to FIG. **1**, a perspective view of an embodiment of a mitral valve implant **10** is depicted. In general, the mitral valve implant **10** may be capable of increasing the sealing

and/or closure of the passage between the left ventricle and the left atrium during contraction of the left ventricle relative to damaged and/or leaking native valve. Accordingly, in some embodiments the mitral valve implant **10** may be capable of operating in combination with a partially operable and/or damaged mitral valve. That is, the mitral valve implant may interact and/or cooperate with at least a portion of the native mitral valve to reduce and/or eliminate excessive regurgitation. As shown, mitral valve implant may generally include a valve body portion **12** which may be coupled to a shaft **14**. The shaft **14** may be coupled to an anchor portion **16**.

The valve body portion **12** of the mitral valve implant **10** shown in FIG. **10** may have a generally tapered shape, including a sidewall **17** tapering outwardly from a narrow portion **18** adjacent to one end of the valve body **12** to an enlarged portion **20** adjacent to the other end of the valve body **12**. The taper of the sidewall **17** may have a flared or belled shape, providing an at least partially concave geometry, as depicted in FIG. **1**. In various other embodiments the valve body may include a sidewall having a generally uniform taper, providing a straight profile. In still other embodiments, the sidewall of the valve body may exhibit a convex taper, producing an at least somewhat bulging tapered profile.

The enlarged portion **20** of the valve body **12** may have an arcuate profile around the circumference **22** of the proximal region of the enlarged portion **20**. The bottom **24** of the enlarged portion **20** may be provided having a flat and/or arcuate shape. Furthermore, the bottom **24** of the proximal region may include convex and/or concave contours.

According to an embodiment, the valve body **12** may be slidably coupled to the shaft **14**. The valve body **12** may include an opening **26** extending from the bottom **24** of the enlarged portion **20**, through the valve body **12**, and to the narrow portion **18**. In one such embodiment, the opening **26** may extend generally axially through the valve body **12**. The opening **26** may be sized to slidably receive at least a portion of the shaft **14** therethrough. The shaft **14** may include one or more stops **28**, **30**. The stops **28**, **30** may be sized and/or shaped to control and/or restrict translation of the valve body **12** along the shaft **14** beyond the respective stops **28**, **30**. In this manner, in the illustrated embodiment, translation of the valve body **12** along the shaft **14** may be restricted to the expanse of the shaft **14** between the stops **28**, **30**.

One or more of the stops **28**, **30** may be integrally formed with the shaft **14**. Furthermore, one or more of the stops **28**, **30** may be provided as a separate member coupled to and/or formed on the shaft **14**. In an embodiment in which one or more of the stops **28**, **30** are integrally formed with the shaft **14**, the valve body **12** may be slidably coupled to the shaft **14** by pressing the valve body **12** over at least one of the stops **28**, **30**, which may at least partially elastically deform the opening **26** to permit passage of at least one of the stops **28**, **30**. Once the one or more of the stops **28**, **30** have been pressed through the opening **26**, the opening **26** may at least partially elastically recover, thereby resisting passage of the one or more stops **28**, **30** back through the opening **26**. Various other arrangements may be employed for providing stops on the shaft and/or for controlling and/or limiting translation of the valve body along the shaft.

The anchor portion **16** may include a helical member **32** coupled to the shaft **14**. As shown, the helical member **32** may be loosely wound such that adjacent turns of the helical member **32** do not contact one another, for example resembling a corkscrew-type configuration. The anchor portion **16** may be engaged with tissue by rotating the anchor portion **16** about the axis of the helical member **32**, thereby advancing the anchor portion **16** into tissue. Consistent with such an embodiment, the anchor portion **16** may resist pulling out from the tissue. The anchor portion **16** may be provided as an extension of the shaft **14** wound in a helical configuration. Consistent with related embodiments, the anchor portion **16** may be formed as a separate feature and may be coupled to the shaft **14**, e.g., using mechanical fasteners, welding, adhesive, etc.

According to various alternative embodiments, the anchor portion may include various configurations capable of being coupled to and/or otherwise attached to native coronary tissue. For example, the anchor portion may include one or more prongs adapted to pierce coronary tissue and to alone, or in conjunction with other features, resist removal of the anchor portion from tissue. For example, the anchor portion may include a plurality of prongs which may engage native coronary tissue. According to various other embodiments, the anchor portion may include features that may facilitate attachment by suturing. Exemplary features to facilitate suturing may include rings or openings, suture penetrable tabs, etc. Various other anchor portions that may allow attachment or coupling to native coronary tissue may also suitably be employed in connection with the present disclosure.

Turning to FIGS. **2** and **3**, the mitral valve implant **10** is shown implanted within a heart **102**. The mitral valve implant **10** may be disposed at least partially within the left ventricle **104** of the heart **102**. As shown, the anchor portion **16** may be engaged with native coronary tissue within and/or adjacent to the left ventricle **104**. The shaft **14**, coupled to the anchor portion **16**, may extend into the left ventricle **104**. The shaft **14** may further extend at least partially within the mitral valve **108**, i.e., the shaft may extend at least partially between the cusps of the mitral valve, and may also extend at least partially into the left atrium **106**. The valve body **12** of the mitral valve implant **10** may be positioned at least partially within the left ventricle **104** with the enlarged portion **20** within the left ventricle **104** and with the narrow portion **18** positioned at least partially within and/or pointed towards the left atrium **106**.

FIG. **2** depicts the heart **102** in a condition in which the pressure of blood within the left atrium **106** is at equal to, or higher than, the pressure of blood within the left ventricle **104**, e.g., during contraction of the left atrium **106**. As shown, when the pressure of blood within the left atrium **106** is greater than or equal to the pressure of blood within the left ventricle **104**, blood may flow from the left atrium **106** into the left ventricle **104**. The pressure differential and/or the flow of blood from the left atrium **106** to the left ventricle **104** may slidably translate the valve body **12** along the shaft **14** toward the left ventricle **104**, in the direction of blood flow between the chambers.

Sliding translation of the valve body **12** along the shaft **14** may at least partially withdraw the valve body **12** from the mitral valve **108** to an open position, as shown. When the valve body is at least partially withdrawn from the mitral valve **108**, a passage may be opened between the valve body **12** and the mitral valve **108**, allowing blood to flow from the left atrium **106** to the left ventricle **104**. Translation of the valve body **12** away from the mitral valve **108** may be controlled and/or limited by the stop **30**. In the open position, the stop **30** may maintain the valve body **12** in general proximity to the mitral valve **108** while still permitting sufficient clearance between the mitral valve **108** and the valve body **12** to permit adequate blood flow from the left atrium **106** to the left ventricle **104**. Additionally, the flow of blood from left atrium to the left ventricle may cause the mitral valve to flare and/or

expand outwardly away from the mitral valve implant, permitting blood flow between the implant and the cusps of the mitral valve.

As the left ventricle **104** contracts, the pressure of blood in the left ventricle **104** may increase such that the blood pressure in the left ventricle **104** is greater than the blood pressure in the left atrium **106**. Additionally, as the pressure of the blood in the left ventricle **104** initially increases above the pressure of the blood in the left atrium **106**, blood may begin to flow towards and/or back into the left atrium **106**. The pressure differential and/or initial flow of blood from the left ventricle **104** into the left atrium **106** may act against the valve body **12** and may translate the valve body **12** toward the left atrium **104**. For example, pressurized blood within the left ventricle **104** may act against the bottom **24** of the valve body **12** inducing sliding translation of the valve body **12** along the shaft **14** toward the left atrium **106**.

Turning to FIG. **3**, the mitral valve implant **10** is shown in a closed position. In the closed position the valve body **12** may be translated toward and/or at least partially into the left atrium **106**. At least a portion of the valve body **12** may interact with, engage, and/or be positioned adjacent to at least a portion of the mitral valve **108**. For example, at least a portion of at least one cusp of the mitral valve **108** may contact at least a portion of the valve body **12**. Engagement between the valve body **12** and the mitral valve **108** may restrict and/or prevent the flow of blood from the left ventricle **104** back into the left atrium **106**.

In addition to the translation of the valve body **12**, the mitral valve **108** may also at least partially close around the valve body **12**, thereby also restricting and/or preventing the flow of blood from the left ventricle **104** to the left atrium **106**. For example, as mentioned above, at least a portion of one or both of the cusps of the mitral valve may contact at least a portion of the valve body. In some embodiments, as the pressure of the blood in the left ventricle **104** increases, the pressure against the bottom **24** of the valve body **12** may increase. The increase in pressure against the bottom **24** of the valve body **12** may, in turn, increase the engagement between the valve body **12** and the mitral valve **108**.

Sliding translation of the valve body **12** toward the left atrium **106** may at least partially be controlled and/or limited by the stop **28** coupled to the shaft **14**. Additionally, translation of the valve body **12** toward the left atrium **106** may be at least partially limited and/or controlled by engagement between the valve body **12** and the mitral valve **108**. One or both of these restrictions on the translation of the valve body **12** may, in some embodiments, prevent the valve body **12** from passing fully into the left atrium **106**. Furthermore, the diameter of the enlarged portion **20** of the valve body **12** may limit and/or restrict the movement of the valve body **12** into the left atrium **106**.

The preceding embodiment may, therefore, provide a mitral valve implant that is slidably translatable relative to the mitral valve to reduce and/or eliminate regurgitation. Further embodiments of a mitral valve implant having a translating valve body may be provided including various alternative valve body configurations. For example, in one embodiment a valve body may be provided generally configured as a disc including generally planar or arcuate top and bottom surfaces. In the same manner as the illustrated embodiment of FIGS. **1-3**, the disc may translate along a shaft between an open position spaced from the mitral valve of the heart and closed position at least partially engaging the mitral valve and/or at least partially obstructing a flow of blood from the left ventricle to the left atrium. Implants employing a valve body having various other geometries, such as spherical, oblong, etc., may also suitably be employed. Furthermore, in addition to the slidably translatable valve body depicted in FIGS. **1-3**, embodiments may be provided in which the valve body is rotatably and/or pivotally translatable to engage and/or interact with at least a portion of the mitral valve.

The illustrated mitral valve implant is shown including only a single anchor portion coupled to a proximal end of the shaft. A mitral valve implant consistent with the present invention may include more than one anchor portion for securing the mitral valve implant to native coronary tissue. Additional anchor portions may be employed to provide more secure coupling of the valve implant to coronary tissue. Furthermore, more than one anchor portion may be employed to achieve more precise positioning of the valve implant and/or the valve body portion of the valve implant within the heart. For example, a replacement valve may include an anchor portion coupled to the proximal end of the shaft and to the distal end of the shaft. In such an embodiment, each end of the shaft may be coupled to native coronary tissue. The orientation of the shaft, and thereby the path of translation of the valve body, may be controlled by coupling each end of the shaft to native coronary tissue. In a similar embodiment, the valve implant may include an anchor portion coupled to one end of the shaft and may include another anchor portion coupled to the shaft between the ends thereof.

A valve implant may be produced from a variety of suitable materials. Generally, such materials maybe be biocompatible. Suitable materials may include biocompatible polymers, such as silicone, polyurethane, etc. Various metals may additionally be used in connection with a valve implant, such as titanium, stainless steel, etc. Additionally, biological materials and/or materials which may promote cellular ingrowth may also be used in connection with a valve implant herein. Furthermore, various combinations of materials may be used herein, e.g., providing composite features and/or portions made from different materials. For example, the shaft may be formed from a metal and the valve body may be formed from a polymeric material. Various additional and/or alternative combinations may also be employed herein.

Turning to FIG. **4**, another embodiment of a mitral valve implant **200** is depicted. The mitral valve implant **200** generally includes a valve body portion **202** coupled to a shaft **204**. The shaft **204** may be coupled to an anchor **206**. The valve body **202** may be coupled to the shaft **204** in a stationary fashion, e.g., the valve body may be coupled to the shaft in a non-slidable manner. Generally, the valve body **202** may be maintained at a generally fixed position on the shaft **204**. The mitral valve implant **200** may be implanted in a heart such that the anchor **206** and the shaft **204** may maintain the valve body **202** in a position relative to various aspects of the coronary anatomy. According to one aspect, the anchor **206** and the shaft **204** may maintain the valve body **202** positioned extending at least partially within the mitral valve.

The valve body **202** may be maintained in a stationary position on the shaft **204** in various ways. For example, valve body **202** may be formed directly on the shaft **205**. Additionally and/or alternatively, the valve body **202** may be adhesively bonded, welded, staked, and/or mechanically fastened to the shaft **204**. Consistent with other embodiments, the shaft may include one or more stops or features which may prevent and/or limit translation of the valve body along the shaft. For example, the shaft may include a stop closely positioned on either end of the valve body, thereby restricting movement of the valve body. The stops may be fixed and/or may be adjustable along the shaft **204**. Various other configurations and/or arrangements may be employed for coupling the valve body **202** in a stationary manner with respect to the shaft **204**.

Similar to previous embodiments, the anchor **206** may be provided having a helical or corkscrew shape. The helical anchor **206** may be engaged with coronary tissue by rotating the anchor **206** about the axis of the helix, thereby driving the anchor **206** into native coronary tissue. Once the anchor has been engaged with native coronary tissue, the anchor **206** may resist axial pull-out from the tissue. The anchor may additionally and/or alternatively be provided having various features and/or configurations. For example, the anchor may be provided having one or more prongs which may pierce and or be embedded in coronary tissue. In one embodiment, the anchor may include a barbed prong which may resist removal of the anchor from the coronary tissue. The anchor may also be provided having suturing features. For example, the anchor may include a tab and/or ring, etc., through which a suture may pass to secure the anchor coronary tissue.

Turning to FIG. **5**, the mitral valve implant **200** is shown implanted within a heart **102**. The mitral valve implant **200** may be positioned extending at least partially into and/or through the mitral valve **108** between the left ventricle **104** and the left atrium **106**. As shown, when the pressure of blood in the left atrium **106** is higher than the pressure of blood in the left ventricle **104**, for example during contraction of the left atrium **106**, the mitral valve **108** may be in an open condition. In an open condition, blood may flow from the left atrium **106** through the mitral valve **108** and around the valve body **202** and into the left atrium **104**.

The anchor **206** may be engaged in native coronary tissue surrounding and/or defining at least a portion of the left ventricle **104**. The valve body **202** may be positioned extending at least partially into and/or through the mitral valve **108** by the shaft **204** extending between the anchor **206** and the valve body **202**. In a related embodiment, the anchor may be engaged in tissue surrounding and/or defining at least a portion of the left atrium. Similar to the preceding embodiment, the valve body **202** may be positioned extending at least partially into and/or through the mitral valve **108** by the shaft **204** extending between the anchor **206** and the valve body **202**.

Consistent with a further embodiment, the mitral valve implant may include more than one anchor for positioning the valve body relative to the mitral valve. For example, the shaft may include an anchor coupled to each end of the shaft. The shaft may be provided extending through the mitral valve, with one anchor being engaged with coronary tissue on the ventricle side of the mitral valve. The other anchor may be engaged with coronary tissue on the atrium side of the mitral valve. As with the previous embodiments, the valve body may be coupled in a stationary position on the shaft, such that the valve body is positioned extending at least partially into and/or at least partially through the mitral valve.

FIG. **6** depicts the mitral valve implant **200** implanted in a heart **102** with the mitral valve **108** in a closed condition. The closed condition of the mitral valve **108** may occur when the pressure of blood in the left ventricle **104** is higher than the pressure of blood in the left atrium **106**. As shown, when the mitral valve **108** is in a closed condition at least a portion of the mitral valve **108** may interact with, engage, and/or seal against the valve body **202** of the mitral valve implant **200**. The presence of the mitral valve implant **200** may reduce the amount of closure of the mitral valve **108** that is necessary to achieve an adequate seal to permit ejection of blood from the ventricle **104** through the aorta **208**, i.e., to prevent and/or reduce mitral regurgitation.

The valve body **202** may be shaped to facilitate the flow of blood from the left atrium **106** to the left ventricle **104** when the mitral valve **108** is open. The valve body **202** may have a generally streamlined shape, allowing the smooth flow of blood around the valve body **202**. Other embodiments of the mitral valve implant may provide less consideration for the flow characteristics of blood flowing around the valve body. The valve body may have a generally cylindrical, prismatic, etc. shape, without limitation.

The performance of the mitral valve implant **200** for reducing and/or eliminating mitral valve regurgitation may be, at least in part, related to the positioning of valve body **202** relative to the mitral valve **108**. In an embodiment consistent with this aspect, during implantation of the mitral valve implant, the valve body **202** may be slidably positionable along the shaft **204**. Once the anchor **206** is engaged with native coronary tissue the valve body **202** may be translated along the shaft **204** and may be positioned relative to the mitral valve **108**, e.g., such that the valve body **202** extends at least partially within the mitral valve **108**. Slidable positioning of the valve body **202** along the shaft **204** after the mitral valve implant **200** has been delivered to the heart **102** may allow the performance of the mitral valve implant **200** to be adjusted. Furthermore, the adjustability of the position of the valve body **202** may accommodate any errors in the position of the anchor **206** in the heart **102**, and/or may render the successful implantation of the mitral valve implant **200** less dependent upon accurate placement of the anchor **206**. Once the valve body **202** has been positioned, the position of the valve body **202** on the shaft **204** may be fixed, e.g. by frictional engagement between the valve body **202** and the shaft **204**, etc.

The illustrated and described embodiments of the mitral valve implant have utilized an implant body coupled to a shaft. The shaft, as used herein, may be a rigid, semi-rigid. In further embodiments, the shaft may be a flexible member. Consistent with such embodiments, the shaft may be a flexible wire or filament, etc. In some embodiments, the flexible wire or filament may be coupled to at least two anchor portions. For example, the flexible wire or filament may extend through the valve body. An anchor may be coupled to the flexible wire or filament on each side of the valve body. For example, the flexible wire or filament may position the valve body relative to the mitral valve and may be coupled to the left ventricle and to the left atrium, on either side of the valve body.

An embodiment of a mitral valve implant including a flexible wire and/or filament may suitably be employed in embodiments including a translating valve body, in which the valve body may slidably translate along the flexible wire or filament. In a related embodiment, the valve body may be non-slidably coupled to the flexible wire or filament. The flexible wire or filament may be provided having a length which may permit the valve body to move toward and away from the mitral valve utilizing the flexibility of the flexible wire or filament.

Furthermore, an embodiment of a mitral valve implant including a flexible wire or filament may also suitably be employed in an embodiment including a generally stationary implant body. According to such an embodiment, the implant body may be generally non-slidably coupled to the flexible wire or filament. The flexible wire or filament may be coupled to native coronary tissue, e.g., via anchor portions, etc., on either side of the valve body. Coupling the flexible wire or filament on either side of the valve body may generally maintain the valve body in a position within and/or relative to the mitral valve.

Turning to FIG. **7**, another embodiment of a mitral valve implant **200***a* is shown. Similar to the previously described embodiment, the mitral valve implant **200***a* may generally

include a valve body **202** configured to reduce and/or eliminate mitral valve regurgitation. In contrast to the preceding embodiment, an anchor **206** may be coupled to the valve body **202**. As shown, the anchor **206** may be directly coupled to the valve body **202** without a shaft extending between the anchor **206** and the valve body **202**.

As mentioned above, various different features and/or arrangements may be used for attaching and/or securing the mitral valve implant relative to coronary anatomy. FIG. **8** depicts another embodiment of a mitral valve implant **200***b* according to the present disclosure including an alternative anchor **206***a*. As shown, the mitral valve implant **200***b* may include a valve body **202** coupled directly to the anchor **206***a*. Alternatively, the valve body may be indirectly coupled to the anchor, e.g., by a shaft. The anchor **206***a* may generally include one or more prongs, stems, etc. **205**. The prong **205** may include one or more barbs **207**. The mitral valve implant **200***b* may be attached and/or secured to native coronary tissue by piercing the anchor **206***a* at least partially into native coronary tissue. The one or more barbs **207** may engage the coronary tissue and resist removal of the anchor **206***a* from the coronary tissue.

In a related embodiment, an anchor including one or more barbs may be employed in connection with a translating mitral valve implant configuration, as shown and described herein. In such and embodiment, the valve body may be translatable relative to the native mitral valve. For example, the valve body may be coupled to the anchor by a shaft extending therebetween. The valve body may be slidable along the shaft, permitting the valve body the translate relative to the mitral valve. Various alternative and/or additional related embodiments may also be provided consistent with this aspect of the present disclosure.

Turning to FIG. **9**, another embodiment of a movable and/or translatable mitral valve implant **10***a* is depicted. Similar to the previously described embodiment, the mitral valve implant **10** may generally include a valve body **12** slidably coupled to a shaft **14**. The mitral valve **10***a* may further include an anchor **16** coupled to the shaft **14** and configured to secure and/or attach the mitral valve implant **10***a* to native coronary tissue. As shown in broken line, the mitral valve implant **10***a* may include a single stop **29** configured to restrict and/or control the range of movement of the valve body **12** along the shaft **14**. As shown, the stop **29** may be disposed at least partially within the valve body **12** and the range of movement of the valve body **12** may be restricted by an interaction between the stop **29** and an inner wall and/or portion of the valve body **12**.

As shown, the shaft **14** may extend at least partially though the valve body **12**, e.g., through respective openings **26** and **27** at opposed ends of the valve body **12**. The stop **29** may be an enlarged region of the shaft **14**, and/or a bead or other member disposed on the shaft **14**. The stop **29** may be dimensioned to prevent and/or restrict passage of the stop **29** through one or both of the openings **26**, **27** in the valve body **12**. The valve body **12** may, therefore, translate along the shaft **14** with the range of movement being controlled and/or restricted by the interaction of the stop **29** and the openings **26**, **27** and/or with an interior wall of the valve body **12**.

According to one embodiment of a mitral valve implant **10***a* including a single stop **29** for controlling the range of movement of the valve body **12**, the stop **29** may be installed inside of the valve body by elastically deforming one of the openings **26**, **27** over the stop **29**. One of the openings **26**, **27** may be elastically deformed by pushing the stop against the opening **26**, **27** causing the valve body **12** to deform and the opening **26**, **27** to expand to permit entrance of the stop **29** into the valve body **12**. The valve body **12** may subsequently at least partially elastically recover to resist subsequent removal of the stop **29** from the valve body **12**. Deformation and/or elastic recovery of the valve body **12** may be aided by heating the valve body and/or the stop. In a related embodiment, the stop may also and/or alternatively elastically deform to permit assembly of the mitral valve implant. Various additional and/or alternative methods may also be employed for forming a mitral valve implant including a single stop for restricting and/or controlling the range of movement of the valve body.

A mitral valve implant according to the present disclosure may be implanted using a variety of surgical an/or non-surgical procedures and/or minimally invasive surgical procedures. A surgical implantation procedure may include, for example, an open heart procedure in which the implant may be directly placed into the heart and manually positioned relative to the mitral valve.

A mitral valve implant consistent with the present disclosure may also advantageously be implanted using less invasive procedures. For example, the mitral valve implant may be implanted using a percutaneous procedure. A suitable percutaneous implantation procedure may include a catheterization procedure. Generally, in a percutaneous catheterization procedure the mitral valve implant may be delivered to the heart using a catheter inserted into a vein or artery, depending upon the desired delivery sight, and into the left atrium or the left ventricle. In one such embodiment, the mitral valve implant may be delivered via a transceptal approach, in which the catheter is inserted, e.g., via a vein, into the right atrium. The catheter may then pass through a puncture between the right atrium to the left atrium and further through the mitral valve to the left ventricle, if desired. Generally, according to a catheterization procedure, the vein or artery may be accessed through a percutaneous incision or puncture. A catheter carrying the mitral valve implant may be introduced into the vein or artery through the incision or puncture. The catheter and mitral valve implant may be passed through the vein or artery into the heart. Once in the heart, the mitral valve implant may be deployed from the catheter and positioned within and/or between the left ventricle and the left atrium.

Turning next to FIG. **10**, an embodiment of a percutaneous delivery system **300** for a mitral valve implant **301** is shown. As previously described, the mitral valve implant **301** may generally include a valve body **302** and an anchor **306**. According to some embodiments, the mitral valve **301** may further include a shaft **304** which is coupled between the valve body **302** and the anchor **306**. As depicted, the mitral valve implant **301** may be loaded into a catheter **308**. According to a further embodiment, the mitral valve implant may be carried by a conveyance feature, such as an enlarged region of a catheter and/or a chamber or pod couple to the catheter.

As generally outlined above, with the mitral valve implant **301** loaded in the catheter **308** and/or within a conveyance feature associated with the catheter, at least a portion of the catheter **308** may be inserted into a vein or artery and passed through the vessels, i.e., veins and/or arteries, to the heart. Conveyance of the catheter **308** and/or of the mitral valve implant **301** to the heart may be directed and/or assisted by monitoring the travel of the catheter **308**, e.g., via radiographic and/or other imaging techniques, etc. For example, at least a portion of the catheter **308** and/or at least a portion of the mitral valve implant **301** may include a radio-opaque material, allowing the position of the catheter **308** and/or of the mitral valve implant **301** to be radiographically monitored or determined.

Once the mitral valve implant **301** has been delivered to the heart, the mitral valve implant **301** may be implanted by positioning and securing the implant **301** within the heart and deploying the implant **301** from the catheter **308**. The implant **301** may be secured within the heart by engaging the anchor **306** with native coronary tissue. Utilizing a helical anchor **306**, as shown, the mitral valve implant **301** may be secured by pressing the anchor **306** into coronary tissue and rotationally advancing the anchor **306** into coronary tissue. Rotationally advancing the anchor **306** may be achieved by rotating the entire catheter **308**, and or at least a portion of the catheter **308**, and thereby also rotating the anchor **306** relative to the coronary tissue. Alternatively, the anchor and/or the entire mitral valve implant may be rotated independently of the catheter, e.g., by a drive lead, such as a flexible drive shaft, extending through at least a portion of the catheter and coupled to the mitral valve implant and/or coupled to the anchor. According to various other embodiments, the anchor of the mitral valve implant may include suturing features, barbs and/or prongs, etc. Suitable corresponding operations may be employed for engaging such anchor features with native coronary tissue.

The mitral valve implant **301** may be deployed from the catheter **308**, or other conveyance feature by pushing the mitral valve implant **301** from the catheter. For example, a pushrod **310**, etc., may extend through at least a portion of the catheter **308**. The pushrod **310** may be axially advanced through the catheter **308** to force the mitral valve implant **301** from the lumen of the catheter **308**. In a related embodiment, the mitral valve implant may be deployed from the catheter via hydraulic force. For example, a fluid may be forced through the catheter. The fluid may bear on, and may hydraulically eject the mitral valve implant from the catheter. In still a further embodiment, the mitral valve implant may be pulled from the catheter. The anchor may be engaged with coronary tissue, and the catheter may be withdrawn from the anchor site, leaving the mitral valve implant engaged with the coronary tissue. Combinations of the foregoing deployment techniques, as well as other known deployment techniques, may also suitable be employed.

The mitral valve implant **301** may be positioned relative to the coronary anatomy before, during or after deployment of the mitral valve implant **301** from the catheter **308**. For example, the anchor portion **306** of the mitral valve implant **301** may be engaged with coronary tissue. The valve body **302** and shaft **304** may then be positioned relative to coronary anatomy by manipulation of the catheter **308**, etc. Once the mitral valve implant **301** has been arranged relative to coronary anatomy, the mitral valve implant **301** may be fully deployed from the catheter **308**. Alternatively, the mitral valve implant **301** may be fully deployed from the catheter **308**. Following deployment, the mitral valve implant **301** may be manipulated to achieve a position and/or arrangement relative to coronary anatomy. Consistent with such an embodiment, the anchor **306** of the mitral valve implant **301** may be engaged with coronary tissue before, during, or after complete deployment of the mitral valve implant **301**. Various other techniques and methods may also suitably be employed.

At least a portion of the mitral valve implant **301** may be collapsible and/or reducible in volume to facilitate percutaneous and/or transluminal delivery. In such a manner, the valve body **302** of the mitral valve implant **301** may be a collapsible member, which can be reduced in volume and/or reduced in maximum diameter during delivery to the heart and/or during placement and/or attachment of the anchor to native coronary tissue. After delivery to the heart, the valve body **302** may be expanded, inflated, and/or otherwise increased in volume or size. Accordingly, the mitral valve implant **301** may be delivered to an implantation site via a smaller diameter catheter, and/or via smaller vessels, than would otherwise be required.

With reference to FIG. **11**, according to one embodiment, the mitral valve implant may include an inflatable valve body **402**. An inflatable valve body **402** may include an at least partially deformable body **404** defining at least one cavity **406**. The body **404** may further define an opening **408** capable of receiving at least a portion of a shaft **410** therein. Additionally or alternatively, the body may include one or more features for coupling the body to a shaft.

The at least partially deformable valve body **404** may be collapsed to a reduced size, which may, for example, allow the valve body **404** to be loaded into a catheter delivery system. Such a catheter delivery system may be suitable for transluminal delivery of a mitral valve implant, including the inflatable valve body **402**, to the heart. In addition to being collapsed, the valve body **402** may be deformed to facilitate loading into a catheter delivery system. For example, the valve body **402** may be collapsed and may be rolled and/or folded to a generally cylindrical shape, allowing the valve body **402** to be loaded in a catheter having a circular lumen.

A collapsed and/or rolled or folded valve body **402** may be inflated, restoring the valve body **402** to expanded configuration. For example, a collapsed and/or rolled or folded valve body **402** may be inflated and restored to an expanded configuration once the mitral valve implant has been delivered to the heart and deployed from a catheter delivery system. Inflating the valve body **402** may be carried out by introducing a fluid, such as saline, into the at least one cavity **406**. In addition to a liquid, such as saline, the valve body may be inflated with a setting or curable fluid. The setting or curable fluid may set and/or be cured to a solid and/or semi-solid state within the cavity of the valve body. An example of such a material may be a thermoset polymer resin, a gel material, such as silicone gel, etc.

According to one embodiment, after delivery to the heart and deployment from the catheter delivery system, the at least one cavity may be filled with a fluid by injecting the fluid into the cavity via a filling tube extending through and/or with the catheter delivery system. Other filling methods and systems may also suitably be employed herein. In an inflated state, the valve body may be shaped and/or configured for use in connection with a translating and/or a stationary mitral valve implant, as described previously.

According to another embodiment, shown in FIG. **12**, the valve body **502** may be expandable. An embodiment of an expandable valve body **502** suitable for use in connection with a mitral valve implant herein may include a recoverably deformable shell **504** defining the shape of the valve body **502**. Similar to previous embodiments, the valve body **502** may include an opening **506** for receiving a shaft **508** of a mitral valve implant at least partially therein. According to one embodiment, the opening **506** may provide a passage extending through the valve body **502**. Additionally and/or alternatively, the valve body may include features for coupling the valve body to the shaft.

The recoverably deformable shell **504** may be deformable, for example, to permit the valve body **502** to be collapsed, folded, rolled, etc., for loading into a catheter delivery system, and/or to facilitate delivery of a mitral valve implant including the valve body **502** to an implantation site, e.g., within the heart. The recoverably deformable shell **504** may further be recoverable, allowing the valve body **502** to return to the expanded configuration from a deformed configuration.

Consistent with one aspect, the deformable shell **504** may include a resiliently deformable material, such as an elastomer, which may be elastically deformed under stress. The deformable shell **504** may elastically recover when the stress is removed. In such an embodiment, the deformable shell **504** may, for example, be deformed from an expanded configuration to a collapsed condition and loaded into a catheter delivery system. After delivery to an implant site, the deformable shell **504** may be deployed from the catheter delivery system, thereby removing the deforming stress from the valve body **502**. Once the deforming stress is removed, the deformable shell **504** may resiliently recover back to the expanded configuration.

In a related embodiment, the deformable shell may include a shape memory material, such as Nitinol, etc. The deformable shell may be collapsed and/or deformed to facilitate delivery of the implant to the desired site, e.g., via a transluminal and/or a surgical procedure. The deformable shell may subsequently be recovered to an expanded configuration. In an embodiment using a thermally activated shape memory material, recovery of the shape memory deformable shell may be accomplished by heating the deformable shell to, or above, an activation temperature. Heat for activating the shape memory material may be provided by the body temperature of the subject receiving the mitral valve implant, and/or from an external source, e.g., via the catheter, etc.

An embodiment of mitral valve implant may include an expandable/recoverable valve body including a cellular material. The cellular material may be, for example, a deformable and/or compressible expanded material, such as a polymeric foam material. The valve body may be deformed, compressed, and/or collapsed to a reduced volume configuration, at least in part, by compressing or deforming the cellular material. The mitral valve implant may be transported to an implant site as disclosed. When the implant is deployed from the delivery system the valve body may recover to a generally original volume and/or configuration. Recovery of the valve body may include recovery and/or expansion of the cellular material.

In another related embodiment, depicted in FIG. **13**, an expandable valve body **602** may include deformable and/or flexible outer shell **604**. The outer shell **604** may be supported in an expanded configuration by one or more recoverably deformable supports. In the embodiment of FIG. **13**, the recoverably deformable support may be provided as a resiliently deformable rib **606**. The deformable shell **604** may be a resiliently deformable material and/or may be a flexible material. The resiliently deformable rib **606** and/or the deformable shell **604** may be deformed, e.g., to collapse the valve body **602** from an expanded configuration, under a deforming stress. As discussed with reference to other embodiments, collapsing the valve body **602** may facilitate transport to an mitral valve implant, for example, using a catheter delivery system. When the deforming stress is released, e.g., by deploying the valve body **602** from a delivery system, the recoverably deformable rib **606** and/or the deformable outer shell **604** may resiliently recover to restore the valve body **602** to an expanded condition. While only a single rib is depicted in the illustrated embodiment, the valve body may alternatively include a plurality of recoverably deformable ribs.

In various embodiments, the recoverably deformable supports may be configured as ribs, generally having a transverse orientation relative to the axis of the valve body, such as depicted in FIG. **13**. In additional and/or alternative embodiments, a valve body **702** may include a deformable and/or flexible outer shell (not shown) covering and/or supported by recoverably deformable supports in the form of resiliently deformable stringers **704**. As depicted in FIG. **14**, the recoverably deformable stringers **704** may be generally oriented along the longitudinal axis of the valve body **702**. In a further embodiment, the recoverably deformable supports may be configured as a lattice, scaffolding, etc. supporting a deformable and/or flexible outer shell of the valve body. Further embodiments may include combinations ribs and stringers. Various other configurations of recoverably deformable supports may also suitably be employed.

In addition to resiliently recoverable shell, supports, etc., a mitral valve implant may include a valve body having an outer shell and/or having supports which may be controllably recoverable. For example, an outer shell and/or one or more supports of a mitral valve implant valve body may be formed from a shape memory material. Such materials may include shape memory metal alloys, shape memory polymers, etc. Consistent with such embodiments, the valve body may be collapsed and/or otherwise deformed from an expanded configuration. The collapsed and/or deformed valve body may maintain the collapsed and/or deformed configuration after the initial deforming stress is released. The valve body may subsequently be returned to the expanded and/or operable configuration, for example, by heating the valve body above an activation temperature of the shape memory material, which may induce recovery of the shape memory material to a pre-deformed shape. The activation temperature inducing recovery of the deformed valve body may be provided by the body temperature of the patient receiving the mitral valve implant. Alternatively, heat for activating recovery of the shape memory material may be provided by a heating element coupled to the valve body and/or a heating element delivered through a catheter. In other embodiments, activating heat may be provided by irradiating the shape memory material, e.g., with microwaves, IR light, etc.

Another embodiment of a valve body **800**, suitable for use in a mitral valve implant, is shown in FIG. **15**. The valve body **800** may include first and second enlarged portions **802**, **804** joined by a narrow region **806**. In one such embodiment, the valve body may have a generally hourglass shape, as shown. The valve body **800** may be positioned relative to a mitral valve such that the first enlarged portion **802** may be disposed at least partially within the left atrium and the second enlarged portion may be disposed at least partially within the left ventricle. The valve body may be maintained in position relative to the coronary anatomy by an anchor and/or a shaft consistent with any preceding embodiment. Additionally, the valve body **800** may be a collapsible and/or expandable member consistent with any previously discussed embodiment.

The implant herein has been disclosed above in the context of a mitral valve implant. An implant consistent with the present disclosure may also suitably be employed in other applications, e.g., as an implant associated with one of the other valves of the heart, etc. The present invention should not, therefore, be construed as being limited to use for reducing and/or preventing regurgitation of the mitral valve.

While the depicted embodiments including expandable and/or recoverably deformable valve bodies have generally been shown configured as a valve body consistent with a stationary valve implant, an expandable and/or recoverably deformable valve body may be configured for use as part of a valve implant including a translating valve body. Similarly, while the valve implant embodiments including an expandable valve body have been discussed in connection with transluminal and/or percutaneous delivery systems and/or procedures, such embodiments may also suitably be employed in connection with surgical delivery systems and/or methods.

Additionally, other features and aspects of the various embodiments may also suitably be combined and/or modified consistent with the present disclosure. The invention herein should not, therefore, be limited to any particular disclosed embodiment, and should be given full scope of the appended claims.

What is claimed is:

1. A heart valve implant comprising:

a shaft extending generally linearly along a longitudinal axis of said heart valve implant, said shaft having a first and a second end disposed generally opposite each other;

an anchor coupled to said first end of said shaft, said anchor comprising one of a helical feature for threadably engaging native coronary tissue or at least one barb for engaging native coronary tissue; and

an inflatable valve body fixably coupled to said second end of said shaft in a stationary position with respect to said second end of said shaft, said valve body configured to be disposed between at least two cusps of a heart valve and to engage against at least a portion of at least one cusp of said heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, wherein said valve body comprises an expandable portion of a shape memory material capable of recoverable deformation;

wherein said heart valve implant is coupled only to native coronary tissue of a left ventricle.

2. A heart valve implant according to claim **1**, wherein said anchor is integral with said shaft.

3. A heart valve implant according to claim **1**, wherein said valve body comprises a tapered portion and an enlarged portion.

4. A heart valve implant according to claim **3**, wherein said enlarged portion is capable of at least partially sealingly engaging said heart valve in said closed position.

5. A method of delivering a heart valve implant comprising:

providing a heart valve implant comprising:

a shaft extending generally linearly along a longitudinal axis, said shaft having a first and a second end disposed generally opposite each other;

an anchor coupled to said first end of said shaft, said anchor comprising one of a helical feature for threadably engaging native coronary tissue or at least one barb for engaging native coronary tissue; and

an inflatable valve body fixably coupled to said second end of said shaft in a stationary position with respect to said second end of said shaft, said valve body configured to be disposed between at least two cusps of a heart valve and to engage against at least a portion of at least one cusp of said heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, wherein said valve body comprises an expandable portion of a shape memory material capable of recoverable deformation;

at least partially collapsing said valve body of said heart valve implant;

percutaneously inserting said at least partially collapsed heart valve implant into a heart;

securing said anchor of said at least partially collapsed heart valve implant only to native coronary tissue of a left ventricle within said heart; and

expanding said at least partially collapsed valve body.

6. A method according to claim **5**, wherein percutaneously inserting said collapsed valve comprises a catheterization intervention.

7. A method according to claim **6**, wherein percutaneously inserting said at least partially collapsed heart valve implant comprises inserting said at least partially collapsed valve into a lumen of a catheter and delivering said valve to said left ventricle via said catheter.

8. A method according to claim **5**, wherein securing said at least partially collapsed heart valve implant comprises coupling said anchor to native coronary tissue.

9. A method according to claim **5**, wherein expanding said valve comprises raising a temperature of said valve body to a temperature equal to, or greater than, an activation temperature of said shape memory material.

10. The heart valve implant of claim **1**, wherein said anchor comprises said helical feature.

11. The heart valve implant of claim **1**, wherein said anchor comprises said at least one barb.

12. The method of claim **5**, wherein said anchor comprises said helical feature.

13. The method of claim **5**, wherein said anchor comprises said at least one barb.

14. The heart valve implant of claim **1**, wherein said valve body is formed directly on said second end of said shaft.

15. The heart valve implant of claim **1**, wherein said valve body is adhesively bonded to said second end of said shaft.

16. The heart valve implant of claim **1**, wherein said valve body is welded to said second end of said shaft.

17. The heart valve implant of claim **1**, wherein said valve body is mechanically fastened to said second end of said shaft.

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